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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,671	04/24/2000	Michael Stephen Austin	792-21 RCE	7622
23869	7590	08/28/2006		
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER REIMERS, ANNETTE R	
			ART UNIT 3733	PAPER NUMBER

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,671

Applicant(s)

AUSTIN, MICHAEL STEPHEN

Examiner

Annette R. Reimers

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-15, 17-24, 27-31, 33-37 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-15, 17-24, 27-31, 33-37, and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 April 2000 and 24 February 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to because they appear to be informal and are difficult to understand. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended."

If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11, 15, 17-24, 27, 31, 33-37 and 42-45 rejected under 35 U.S.C. 102(b) as being anticipated by Maass et al (US Patent Number 4,553,545)

Maass et al. disclose an endoluminal prosthesis, 1, comprising a proximal end, a distal end and a hollow tubular body comprising a stent scaffold, the stent scaffold consisting essentially of undulating wires having turns, the hollow tubular body comprising at least one segment of curvature, the segment of curvature comprising an inside of the curvature and an outside of the curvature, wherein the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature to provide a constant pitch of the wires therealong (see figures 4-7). In addition, the wires can have an increased pitch at the outside segment and have a reduced pitch at the inside segment when disposed on a straight mandrel and wherein the increased pitch at the outside segment is relative to the reduced pitch at the inside segment. (see various embodiments, e.g. figure 1).

The segment of curvature is curved in at least one plane with respect to the central axis of the body, the segment of curvature is curved in at least two planes with

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respect to the central axis of the body, the hollow tubular body has at least two segments of curvature wherein the segments of curvature are located in successive progression along the body of the prosthesis and the segments are curved within the same plane of curvature, the hollow tubular body has at least two segments of curvature wherein the segments of curvature are located in successive progression along the body of the prosthesis and the segments are curved within different planes of curvature, the hollow tubular body has at least two segments of curvature wherein the segments of curvature overlap at least a portion of one another and the segments of curvature are curved within different planes of curvature, comprising segments of curvature which overlap and segments of curvature which do not overlap (see various embodiments of figures 1-11, 13A, 14 and 22-27).

The prosthesis comprises at least one segment of curvature to approximate an anatomical shape, wherein the prosthesis approximates the anatomical shape of the anatomical site intended for placement of the prosthesis (see column 5, lines 32-65). Maass et al. disclose the use of a shape memory alloy (see column 1, lines 47-50). The hollow tubular body comprises a thin-walled tube material, e.g. 37, wherein the center of the thin-walled tube provides the center of the prosthesis. The prosthesis comprises at least one taper along the length of the body, the prosthesis comprises at least one aperture on the body between the proximal end and the distal end, the prosthesis comprises at least one non-circular cross-section along the length of the body and the prosthesis further comprises at least one branch of the prosthesis that extends away

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from the body of the prosthesis (see figures 22-27). At least a portion of the prosthesis is covered with a graft covering (see column 17, lines 13-25).

With regard to the statement of intended use and other functional statements, e.g. "the wires can have an increased pitch at the outside segment and have a reduced pitch at the inside segment when disposed on a straight mandrel", they do not impose any structural limitations on the claims distinguishable over Maass et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 12, 13, 14, 28, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maass et al. (US Patent Number 4,553,545) in view of MacGregor (US Patent Number 4,994,071), cited by applicant.

Maass et al. disclose the claimed invention except for the specific materials of the self-expanding stent, e.g. super elastic alloys, polymers, and nitinol. MacGregor teaches that many different materials may be selected to be used in a stent including super elastic alloys, polymers, and nitinol and teaches the use of these materials in order to vary springiness, malleability, bioabsorbability, or biodegradability and response to temperature (see column 5, lines 38-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Maass et al. with a different material, in view of MacGregor, in order to vary springiness, malleability, bioabsorbability, or biodegradability and response to temperature

Response to Arguments

Applicant's arguments with respect to claims 1-9, 11-15, 17-24, 27-31 and 33-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER